ARNOLD & PORTER
555 TWELFTH STREET, N.W.
WASHINGTON, D.C. 20004-1202
(202) 942-5000
FACSIMILE: (202) 942-5999

NEW YORK
DENVER
LOS ANGELES
LONDON

DONALD O. BEERS
(202) 942-5012

February 3, 2000

Dockets Management Branch
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20857

Re: Petition for Stay; NDA 20-932

Dear Sir or Madam:

On behalf of Roxane Laboratories, Inc., the applicant for the above-referenced new drug application, we petition the Food and Drug Administration to stay the effective date of that new drug application under 21 C.F.R. 10.35. We request that the stay be until such time as Roxane Laboratories submits additional data, FDA has reviewed those data and has determined that those data support the conclusion that the drug covered by the application has been shown to be safe and effective, and the labeling for the drug has been revised to reflect those data. We understand that the revised labeling will make it clear that neither the applicant nor FDA rely, in the determination that the drug covered by the NDA is safe and effective, on any investigations as to which Roxane does not have a right of reference. It is understood that the drug covered by the NDA will not be marketed during the pendency of the stay.

Respectfully submitted,

Donald O. Beers

Donald O. Beers

99P-1589

PSA2